K072404

ERBE USA Incorporated **CONFIDENTIAL**
Abbreviated 510(k) – ERBE ERBEJET® 2 System

510K SUMMARY

OCT 31 2007

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal QA/RA Manager
Date Prepared:	August 23, 2007
Common Name:	Water Jet Dissector
Trade/Proprietary Name:	ERBE ERBEJET® 2 System
Classification Name:	Jet Lavage (21 CFR Part 880.5475)
Product Code:	FQH
Legally Marketed Predicate Devices:	ERBE Helix Hydro-Jet™ System, 510(k) Numbers: K033590; K022613; K012464

Device Description:

The ERBEJET® 2 System delivers pressurized normal saline solution (0.9% saline solution for irrigation) to cut and dissect soft tissue. The ERBEJET® 2 Unit together with its accessories is an active invasive surgical product. The sterile normal saline solution is the "cutting medium" which is projected under pressure through a nozzle. The pressure is generated by a sterile single-use double piston Pump Cartridge and is controlled by means of a Footswitch. The Footswitch has a "ReMode" button that allows the user to switch between two established or "set" programs during the surgical procedure. The ERBEJET® 2 Unit has a display screen that allows the user to adjust the desired pressure settings using effect levels (1 to 80). The user may use the BASIC program that comes preprogrammed or set up to nine additional personalized programs. The cutting medium is isolated from the pressure generation Unit (i.e. the ERBEJET® 2 Unit) except at the sterile Pump Cartridge. A range of Applicators with a nozzle diameter of 120 µm is available for a wide range of applications. An integrated suction function (i.e. the Suction Module, Model ESM 2 which is separate and optional) can be used with the Unit and is adjustable up to -12 psi. Settings for the suction are adjusted on the display screen of the ERBEJET® 2 Unit.

Intended Use:

The ERBEJET® 2 System is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.

510K SUMMARY

Similarities and Differences of the Proposed Devices to the Predicate Devices Comparison/Substantial Equivalence):

Similarities

The ERBEJET® 2 System has the same indications for use as the predicate device. The mechanical and technical aspects of creating the pressurized "cutting medium" have changed; however, the performance (i.e. the pressure and volume flow) is substantially equivalent. See Section I, Chart on I-10 as well as Section III, Comparison of System Outputs and Performance Testing. The Applicators are similar to the predicate device with slight differences. See Section III, Comparison Table. However, the volume flow and pressures through the nozzle are equivalent. Under testing, the ERBEJET® 2 System shows improved linear distribution than the predicate device. See Section I, Chart on I-10. Although the suction pump (i.e. Suction Module, Model ESM 2) is separate from the ERBEJET® 2 Unit, the functions are integrated into the ERBEJET® 2 Unit via its display screen which is equivalent to the predicate device. While both systems have a display screen, the display of the ERBEJET® 2 Unit is easier for the user to understand and navigate through.

Differences

The ERBEJET® 2 System uses a two head piston Pump Cartridge to create the pressurized "cutting medium" while the predicate device uses a hydraulic piston. The predicate device has a high-pressure range up to 2,175 psi; however, it was determined by user feedback that this high-pressure range was not utilized. The modified device has a high-pressure range up to 1,160 psi (80 bar). With the removal of the large hydraulic piston, the size and weight of the ERBEJET® 2 Unit has decreased substantially and the maintenance of the proposed unit has improved because there is no hydraulic oil to change. The Applicators have differences in materials, which were tested under biocompatibility. See Section III, Biocompatibility. In addition, the Applicators have slight differences in their dimensions. See Section III, Comparison Table. The changes were made as a result of user feedback. There is a small amount of fluid, less than 0.2 ml, released at the end of activation with the ERBEJET® 2 System due to the way the flow shutoff valves close off. Conversely, the Helix Hydro-Jet has shown almost no water released at the end of activation. No safety or efficacy issues are expected from the release of the small amount of residual fluid at the end of activation with the ERBEJET® 2 System.

The ERBEJET® 2 System has been verified or validated in design control by ERBE Elektromedizin GmbH.

Conclusion:

The ERBEJET® 2 System has the same intended use, principles of operation, and technological characteristics as the predicate device. The ERBEJET® 2 System is smaller and easier to use. In conclusion, all the changes were verified or validated. As a result, the changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness.

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
Manufacturer	HumanMed AG [Used to be Andreas Pein Medizintechnik GmbH]	ERBE Elektromedizin GmbH
510(k) Applicant	ERBE USA, Inc. and Andreas Pein Medizintechnik GmbH	ERBE USA, Inc.
510(k) Number	K033590; K022613; K012464	Pending
Classification Regulation Product Code, Name	Class II, 21 CFR 880.5475 FQH, Jet Lavage	Same
Device Name	Helix Hydro-Jet™ System [Includes Fluid Cartridge, Applicators, etc.]	ERBEJET® 2 System [Includes Pump Cartridge, Applicators, Separate/Optional Suction Module ESM 2, etc.]
Indications For Use	The Helix Hydro-Jet™ is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.	Same
Materials		
• Unit	Metal Sheet, Glass Display Screen, Plastics, Wiring	Same
• Components		
▫ Connecting Cables	Insulation Plastic, Wiring, Metals	Same
▫ Footswitch	Aluminum, Plastics, Insulation Plastics, Rubber	Same
▫ Fluid (Application) Cartridge	0.9% Normal Saline Solution, Plastics (Polyethylene), Silicone	Not Applicable
▫ Pump Cartridge	Not Applicable	Plastics (PA, TPE, PC, PVC), Silicone
▫ Applicators	Plastics (PEEK, PA, PVC), Stainless Steel, Silicone, Synthetic Jewel (Corundum)	Plastics (ABS, PA, PVC), Stainless Steel, Silicone, Rubber, Synthetic Jewel (Corundum)
▫ Suction Module (ESM 2)	The suction system of the Helix Hydro-Jet™ is integrated inside the Unit's case (see above).	Metal Sheet, Plastics, Wiring

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
▫ Suction Accessories	Container and Top: Polycarbonate and thermoplastic elastomer Bag: Two layers (Polyethylene inner lining with polypropylene) Hose: Silicone, Rubber O-rings Filter: Not Applicable Switching Valve: Not Applicable Rails & Brackets: Not Applicable	Container: Shock-resistant polycarbonate Top: Reinforced polyamide with santoprene seal Bag: Three layers for durability and odor protection (polyethylene/ polyamide / polyester) Hose: Silicone, Rubber O-rings Filter: Plastics Switching Valve: Plastics Rails & Brackets: Aluminum Note: The suction accessories are manufactured by Medela AG in Switzerland (see additional information at the end of the Table).
Physical and Dimensional Attributes		
• Unit		
▫ Length	13.8" (35 cm)	14.6" (37 cm)
▫ Width	13.8" (35 cm)	16.1" (41 cm)
▫ Height	4.0' (122 cm)	5.1" (13 cm)
▫ Mounting	Included, 19.6" (50 cm) x 19.6" (50 cm) [Base including wheels]	Mountable to VIO Cart or Boom
▫ Weight	163 lbs (74 kg)	24.3 lbs (11kg)
• Components		
▫ Connecting Cables	Main Cable (Power Cord), UL-Version, Length 4 m (13.2')	Same
	Not Applicable – Suction is integrated inside the Unit	ECB Connecting Cable, Connects ERBEJET 2 with Suction Module, ESM 2
▫ Footswitch	One Pedal Footswitch, AP and IP X8 Equipment	One Pedal Footswitch, AP and IP X8 Equipment, with ReMode
▫ Fluid Cartridge	Sterile 0.9% Normal Saline Solution in Plastic Bottle, 485 ml	Not Applicable (see Pump Cartridge)

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
▫ Pump Cartridge	Not Applicable (see Fluid Cartridge)	User connects Sterile 0.9% Normal Saline Solution for Irrigation to Pump Cartridge; Saline is purchased separately from other sources
▫ Applicators	Applicator, Blunt Dissector, Outer Diameter (OD) 5mm x Length 180mm, Curved Tip	Same - except Length 183mm
	Applicator, Blunt Dissector, Outer Diameter (OD) 5mm x Length 336mm, Curved Tip	Same
	Applicator with Suction, Length 60 mm Flexible Sheath/Rigid Tip	Same - except Length 65 mm
	Applicator with Suction, Outer Diameter (OD) 6 mm x Length 300 mm Rigid Sheath/Tip	Same - except Length 306 mm
	Applicator with Suction, Outer Diameter (OD) 2,6 mm x Length 60 mm Bayonet Sheath/Tip	Same - except O.D. 2.8 mm and Length 90 mm
▫ Suction System	Integrated within the Helix Hydro-Jet Unit	Integrated for use with the ERBEJET 2 Unit but separate/ optional module - ESM 2
	Suction Container (2,000 ml)	ESM Suction Container (2,000 ml)
	Suction Bag (2,000 ml)	ESM Suction Bag (2,000 ml)
	Suction Container Top (included with Suction Container above)	ESM Suction Container Top (sold separately from Container)
	Suction Hose	ESM Suction Hose, Length 30 cm
	Not Applicable	ESM Membrane Filter, 0.3 µm
	Not Applicable	Switching Valve w/ Suction Hoses & Mounting Bracket
	Not Applicable	Mounting Bracket to Connect to Side Rails
	Not Applicable	Brackets/Side Rails, Length 260 mm and 390 mm
Energy Delivered	Pressurized sterile saline for cutting and dissecting	Same
Supply Voltage and Current	100-120 V; 10 A	120-240 V; 3 A
Frequency	60 Hz	Same

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
Pressure Range	1 to 2,175 psi	14.5 to 1,160.3 psi
Suction Range	-1.45 to -11.6 psi (-12 psi on display)	Same
Nozzle Diameter	120 µm	Same
Volume Flow	1 to 55 ml/min (As measured within same pressure range as the proposed device)	1 to 55 ml/min
Target Population	Patients requiring open or endoscopic surgery in neurosurgery and in and around the abdomen	Same
Anatomical Sites	Soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery	Same
Condition Provided and Method of Sterilization As Applicable		
• Unit, Connecting Cables, Footswitches	Non-Sterile, Reusable	Same
• Fluid Cartridge	Sterile, Single-Use, Radiation (R)	Not Applicable
• Pump Cartridge	Not Applicable	Sterile, Single-Use, Radiation (R)
• Applicators	Sterile, Single-Use, Ethylene Oxide (EO)	Same
• Suction System Unit/Module Bags Containers and Hoses	Within Helix Unit (see above) Non-Sterile, Disposable Non-Sterile, Reusable	Non-Sterile, Reusable Same Same (includes Brackets/Rails)
Performance Standards Met	EN 60601-1; UL 2601-1; EN 60601-1-2; IEC 60529 (Footswitch Only)	EN 60601-1; UL 60601-1; EN 60601-1-1; EN 60601-1-2; EN 60601-1-4; EN 60601-1-6; EN ISO 10079-1; IEC 60529 (Footswitch Only)
Other Standards Used or Applied/Met	ISO 10993-1; ISO 10993-4; ISO-10993-5; ISO 10993-10; ISO 10993-11; EN 556; EN 980; EN 868-1; EN 550; EN 552; EN 1441	Same except for replaced or newer standards: ISO 11607; ISO 14971

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
FDA Guidance Documents Used	• Not Known • General Principles of Software Validation, Version 1.1, dated June 9, 1997 • Guidance for FDA Reviewers and Industry; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998	• Guidance Document for Powered Suction Pump 510(k)s: Sep. 30, 1998 • General Principles of Software Validation; Final Guidance for Industry and FDA Staff; Jan. 11, 2002 • Guidance for FDA Reviewers and Industry; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 11, 2005
Packaging and Labeling	▪ Unit ▫ Unit Label ▫ Instruction Sheet/Quick Guide ▫ User Manual ▪ Components ▫ Not Applicable ▫ Not Applicable ▫ Applicators Outer Package Labels ▫ Applicators Notes on Use Labeling ▫ Fluid Cartridge Outer Package Labels ▫ Fluid Cartridge Notes on Use Labeling ▫ Not Applicable ▫ Not Applicable ▫ Suction Accessories Outer Package Labels ▫ Not Applicable	▪ Unit ▫ Unit Label ▫ Not Available ▫ User Manual ▪ Components ▫ ESM 2 Module Label ▫ ESM 2 User Manual ▫ Applicators Outer Package Labels ▫ Applicators Notes on Use Labeling ▫ Not Applicable ▫ Not Applicable ▫ Pump Cartridge Outer Package Labels ▫ Pump Cartridge Notes on Use Labeling ▫ Suction Accessories Outer Package Labels ▫ ESM 2 Filter Package Label

Suction Accessories:
Medela AG 3002807523 in Switzerland has 510(k)s for their "powered suction pumps" under the product code "BTA" [510(k) # K061205 for the Vario 8/18ci Systems and 510(k) # K043544 for the Dominant 35c/i System] which includes their suction accessories. The ESM 2 suction module is designed and manufactured by ERBE Elektromedizin GmbH and distributed by ERBE USA, Inc. The suction accessories that are being recommended and distributed for use with the ESM 2 suction module are the Medela AG suction accessories as designated under the Medela AG 510(k)s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2007

ERBE USA Inc.
% Mr. John Tartal
QA/RA Manager
2225 Northwest Parkway
Marietta, Georgia 30067-9317

Re: K072404
Trade/Device Name: ERBE USA, Inc.'s ERBEJET® 2 System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH
Dated: August 23, 2007
Received: August 27, 2007

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 072404

Device Name: ERBE USA, Inc.'s ERBEJET® 2 System

Indications For Use:

The ERBEJET® 2 System is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Milhern

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K 072404